

REMARKS

Claims 1 and 4-10 are currently pending in this application. Reconsideration of the present application, in light of the following remarks, is respectfully requested.

Independent claim 1 recites an implantable cardiac lead comprising, *inter alia*, a connector assembly “having an engagement stem depending proximally therefrom, wherein the guidewire lumen and the fluid delivery lumen of the lead body extend through the engagement stem of the connector assembly, and wherein the engagement stem includes a proximal tip portion and a threaded engagement portion integrally formed with the engagement stem, longitudinally distal to the proximal tip portion thereof....”

Claim Rejections Under 35 U.S.C. § 103

Claims 1 and 4-10 have been rejected under 35 U.S.C. § 103, as allegedly being unpatentable over U.S. Patent Publication No. 2002/0077684 to Clemens et al. (“Clemens”) in view of U.S. Patent Publication No. 2002/0077683 to Westlund et al. (“Westlund”). Applicant respectfully traverses this rejection.

Clemens has been relied upon by the Office Action for disclosing the majority of elements recited in independent claim 1. Westlund has been relied upon for disclosing a threaded connection, which the Office Action argues, in combination with the teachings of Clemens, renders Applicant’s claims 1 and 4-10 obvious.

Clemens describes a lead body (12) with a plurality of lumens extending therethrough and an adapter (58) having a plurality of ports. Clemens fails to provide any detailed written description or illustration of the manner in which the lumens of the lead body communicate with the ports of the adapter, beyond that the “lead 10 ...may also include an adapter 58 for coupling to terminal pin 54.” See Clemens, Par. 31. That is, as best as can be determined, the terminal pin (54) is inserted into the adapter (58), and it is the terminal pin (54) alone that engages the adapter (58). See Clemens, par. 30 and Fig. 1. Clemens does not disclose teach or suggest a threaded engagement between the lead (10) and the adapter (58), as required

by Applicant's independent claim 1, as currently presented. More specifically, Clemens does not disclose, teach or suggest "an engagement stem [including] a proximal tip portion and a threaded engagement portion integrally formed with the engagement stem, longitudinally distal to the proximal tip portion thereof..." as recited in independent claim 1.

Westlund, similarly, describes a terminal pin (860) that is engaged with a seal mechanism (820). Figure 9 of Westlund illustrates the seal mechanism (820), including a body (830), a locking hub (821) and an elastomeric grommet (822). The locking hub (821) is connected by way of threads to the body portion (830). The elastomeric grommet (822) is in contact with the terminal pin (860) of the lead, and is compressed around the terminal pin (860) to form a seal therebetween. Neither the threaded locking hub (821), nor the body (830) of the seal mechanism (820) is part of, nor do these elements even come in contact with the lead or the terminal pin (860) thereof. Accordingly, as with Clemens, Westlund does not disclose, teach or suggest "an engagement stem [including] a proximal tip portion and a threaded engagement portion integrally formed with the engagement stem, longitudinally distal to the proximal tip portion thereof..." as recited in independent claim 1. Moreover, neither Clemens, nor Westlund in combination disclose, teach or suggest "an engagement stem [including] a proximal tip portion and a threaded engagement portion integrally formed with the engagement stem, longitudinally distal to the proximal tip portion thereof..." as recited in independent claim 1.

With regard to Westlund, the Office Action states, at page 2

... in response to applicant's argument that the threaded engagement portion taught by Westlund is not integrally formed with the engagement [stem], the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *in re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Westlund teaches that it was known at the time of the invention to provide a threaded engagement portion on the engagement portion of a connector assembly in order to connect an elongated lead body to a ported connector." (emphasis added) See Office Action at page 2.

However, Applicant respectfully submits that “All words in a claim must be considered in judging the patentability of that claim against the prior art.” See MPEP §2143.03, *citing* In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Although the Office Action argues that “Westlund teaches that it was known at the time of the invention to provide a threaded engagement portion on the engagement portion of a connector assembly in order to connect an elongated lead body to a ported connector,” [emphasis added] as set forth above, the threaded engagement portions in Westlund are on the locking hub (821) and body (830) of the seal mechanism (820), and not on the terminal pin (860), lead body or any other contiguous, integral element that would lead one to reasonably consider the threaded engagement portion to be “on” the engagement portion. As set forth above, the locking hub 821 of Westlund, is in no manner in contact with, or integrally formed with, the terminal pin (860) of Westlund. See Specification, page 7, paragraph 1 (paragraph [0026] of the published application).

Accordingly, Applicant again respectfully submits that Westlund, alone or in combination with Clemens, does not disclose, teach or suggest “an engagement stem [including] a proximal tip portion and a threaded engagement portion integrally formed with the engagement stem, longitudinally distal to the proximal tip portion thereof...” as recited in independent claim 1.

For at least the foregoing reasons, it is respectfully submitted that amended independent Claim 1, and each claim depending therefrom, define patentable subject matter over Clemens and Westlund, considered alone or in combination. Withdrawal of the rejection of claims 1 and 4-10 under 35 U.S.C. §103(a) over Clemens and Westlund is therefore respectfully requested.

Dated: April 14, 2008

Respectfully submitted,

By: /Michael J. Pollack/
Michael J. Pollack
Registration No.: 53, 475

EDWARDS ANGELL PALMER & DODGE
LLP
P.O. Box 55874
Boston, Massachusetts 02205
(203) 353-6848
Attorneys/Agents For Applicant